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14. ABSTRACT Unemployed Veterans with posttraumatic stress disorder (PTSD) were prospectively randomized into a multi-site study comparing Individual Placement and Support (IPS), an evidenced-based model of supported employment, to VA vocational rehabilitation treatment-as-usual (VRP-TAU). Over the course of the 52-week follow-up, 25 of the 48 IPS participants (52%) gained competitive employment, compared with 15 of the 46 VRP-TAU participants (33%) ( $\chi^2 = 3.64$ , $df=1$ , $p=.056$ ). That is, Veterans with PTSD who participated in IPS were 1.7 times more likely to gain competitive employment than those who received VRP-TAU. The number-needed-to-treat (NNT) was 5.26. The IPS and VRP-TAU participants worked in a competitive job an average of 23% and 13% of the eligible weeks, respectively (Mann-Whitney z test, $p=0.10$ ). There were no statistically significant between-group differences in terms of number of weeks, days, or hours worked, or the amount of income earned. The IPS group achieved competitive employment significantly more quickly than VRP-TAU (log-rank $\chi^2 = 4.25$ , $p=0.04$ ). Most job acquisition in IPS group occurred within the first 25 weeks. There were no significant differences between groups in terms of PTSD, depression, or quality of life rating scales. A large-scale randomized controlled study of IPS has been launched by the VA Cooperative Studies Program to further evaluate the effectiveness of IPS in Veterans with PTSD.					
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## INTRODUCTION

Posttraumatic stress disorder (PTSD) affects more than 600,000 US Veterans and is the most common psychiatric condition for which Veterans seek VA disability benefits, making up a substantial proportion of the \$23 billion pensions and disability annual budget. Although many Veterans with PTSD are college educated, almost 40% are impoverished, and most report work, role and social functioning scores below those of persons with serious mental illness. According to the VA Fiscal Year 2009 “Long Journey Home” Report (Desia 2013), 61% of Veterans entering specialized outpatient PTSD programs were not working, either due to inability to find work (27%), not looking for work (25%), retirement (26%), or 100% disability (22%). Veterans returning from Iraq and Afghanistan wars often confront unemployment, as evidenced by 2013 unemployment rates of 9% for OIF/OEF/OND Veterans compared to 7.2% for nonveterans (US Department of Labor 2013). The current VA Transitional Work Program (TWP) and other Compensated Work Therapy programs do not sufficiently meet the vocational rehabilitation needs of Veterans (Resnick and Rosenheck 2008), thus, leaving the majority of Veterans vulnerable to continued unemployment and a deteriorating trajectory. Over the past two decades, studies of Individual Placement and Support (IPS) supported employment involving persons with a serious mental illness (SMI; i.e. schizophrenia, schizoaffective, bipolar I disorder, and major depression with psychotic features) have yielded remarkably robust and consistent outcomes (Drake et al 2003; Becker et al 2007, Salyer et al 2004). In the first study of IPS for Veterans with posttraumatic stress disorder (PTSD), 76% of the those randomized to IPS gain competitive employment, compared to 28% of those randomized to conventional VA vocational rehabilitation program (Davis et al 2012). Given these findings, additional controlled studies of IPS were warranted.

Clinical investigators at three Veterans Affairs Medical Centers (VAMC) conducted a multi-site, 52-week prospective, randomized (1:1) study to compare IPS, an evidenced-based model of supported employment, and vocational rehabilitation treatment-as-usual (VRP-TAU) in unemployed Veterans with PTSD. Employment outcomes were assessed over a fixed 12-month observation period and defined as percent of subjects competitively employed for at least one week (primary outcome), and as the number of weeks competitively employed (secondary outcome). Participants were followed for 12 months, regardless of type of discharge or early drop-out from the assigned intervention.

## BODY

### Background

Over the past two decades of studies, the Individual Placement and Support (IPS) model of Supported Employment has yielded remarkably robust and consistent employment outcomes for individuals with serious mental illness (defined as schizophrenia, schizoaffective disorder, bipolar disorder, and major depression with psychotic features). Overall, approximately two-thirds of participants in clinical trials with serious mental illness who received IPS achieved competitive employment. The IPS model is based on A Working Life by Becker and Drake (2003) and a tabulated 3-ring binder IPS manual from web site of the Substance Abuse and Mental Health Services Administration. The IPS model involves the following important features: 1) eligibility is

based on consumer choice, 2) IPS specialist who is integrated into the clinical treatment, carries out all phases of the vocational services, provides predominantly community-based services, provides assertive engagement and outreach, and has a case load of  $\leq 25$  clients; 3) integration within the same system affiliated with the mental health treatment programs 4) rapid job search, individualized placement in diverse and potentially permanent competitive job(s), ongoing work-based vocational assessment, and assistance in finding subsequent jobs if needed with the view that all jobs are positive learning experiences; 5) continuous time-unlimited follow-along supports to provide vocational services (i.e. vocational counseling, job coaching, transportation, intervening with an employer if the Veteran agrees, meeting with client in the community or work setting, networking supports); and 6) weekly group supervision with IPS-SE team and with an IPS supervisor/trainer monthly.

The VA Vocational Rehabilitation Program (treatment-as-usual) model includes the following services: 1) Vocational Assistance Program (i.e. prevocational testing and evaluation), 2) Vocational Rehabilitation Therapy that operates under the Compensated Work Therapy/Veterans Industries (CWT) and provides a work regimen with monetary incentives derived from contracts whereby participants are paid on a piece rate basis related to their production, and 3) Transitional Work Program (TWP) that includes a temporary work experience either within the VAMC or in community settings (called the Transitional Work Program/External or TWP/TWE). The treatment model involves the following important features: 1) vocational rehabilitation employment specialist, who a consultant to the treatment team, carries out some, but not all, phases of the vocational services; provides some community-based services (if temporary work setting is external to the VAMC); provides time-limited assertive engagement and outreach to help the client obtain competitive employment; and has no maximum case load (i.e. often  $>25$  clients at once); 2) step-wise approach to job placement with initial short-term transitional work experiences in an actual work settings (such as VAMC Environmental Management, food, delivery, or clerical services) that are not necessarily individualized to the patient's long-term preferences; job search for placement in potentially permanent competitive job(s) that is delayed until after the transitional work experience is nearly completed; and no long-term follow-up vocational assistance after the first job is obtained; 3) time-limited follow-along supports only during the transitional work experience to provide vocational services (i.e. vocational counseling, job coaching, transportation, intervening with an employer if patient agrees, meeting with client in the community or work setting, networking supports); 4) limited integration within the same system as the mental health treatment programs, and 5) weekly group supervision with VRP team.

### **Investigative Team and Start-up Activities**

"The Impact of Supported Employment versus Standard Vocational Rehabilitation for Veterans with PTSD" study was led by the Principal Investigator (PI) Lori L. Davis, M.D. at the Tuscaloosa VAMC, Tuscaloosa, AL, in collaboration with the partnering PIs Pamela E. Parker, M.D. at the Birmingham VAMC, Birmingham, AL and Charles Drebing, M.D. at the Edith Nourse Rodgers Memorial VA Hospital, Bedford, MA. Each site employed a Clinical Research Coordinator (CRC) for participant recruitment, retention, and data collection, Research Assistant (RA) for blinded clinical assessments and data entry, and an IPS Specialist for the purposes of providing the study intervention. The Project Manager (Catherine Blansett, PhD) was based at the Tuscaloosa VAMC.

Al Bartolucci, Ph.D. and the late Andrew C. Leon, Ph.D. served as the biostatisticians. Rich Toscano, M.Ed. served as a Co-investigator on this study, as well as the IPS Supervisor and Fidelity Monitor. The primary IPS expert consultant was Robert Drake, M.D., Ph.D., Professor of Psychiatry and of Community and Family Medicine at Dartmouth Medical School and Director of New Hampshire-Dartmouth Psychiatric Research Center.

In 2008, Dr. Davis and her staff conducted a start-up training meeting involving each participating medical center prior to the launch of each site. During these start-up meetings, the research teams reviewed the protocol, consent form, case report forms, data collection procedures, principals of IPS supportive employment intervention, vocational rehabilitation treatment-as-usual procedures, and all diagnostic and rating scales. As lead site, Tuscaloosa VAMC coordinated the administrative efforts of all partnering VA Medical Centers (Tuscaloosa, AL; Birmingham, AL; and Bedford, MA). A customized Microsoft Access database application was created to allow for accurate data entry from case report forms and to provide greater matching consistency between the Participant Job Logs and the Employment Index (the form used to record data from the Participant Job Logs). In addition to the Access database, an Excel spreadsheet was used to track recruitment and retention.

### Human Subject Approvals

The “Impact of Supported Employment versus Standard Vocational Rehabilitation for Veterans with PTSD” (W81XWH-08-2-0103) was accepted for funding on April 18, 2008 and approved by the Human Research Protection Office (HRPO), Office of Research Protections, USAMRMC, on May 12, 2008. All sites submitted an abstract, protocol, and consent form, modeled after the approved USAMRMC protocol and consent form, to their local Institutional Review Boards (IRB). All local VAMCs’ IRBs and Research and Development Committees approved the study. The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice Guidelines. All study sites maintained approved IRB status under continuing review throughout the course of the study. Table 1 shows the dates of approvals and numbers enrolled.

<b>Table 1. Dates of Approval and Enrollment for W81XWH-08-2-0103</b>						
<b>Site Name</b>	<b>PI</b>	<b>IRB Approval</b>	<b>USAMRMC Approval</b>	<b>Date of 1<sup>st</sup> Enrollment</b>	<b>Enrolled</b>	<b>Randomized</b>
Tuscaloosa VAMC	Davis	7/3/2008	8/4/2008	**Apr 2009	49	33
Birmingham VAMC	Parker	6/13/2008	9/8/2008	Sept 2008	32	28
Edith Nourse Rodgers Veterans Memorial Hospital	Drebing	8/28/2008	11/20/2008	Nov 2008	45	34
<b>Total Enrolled</b>					<b>126</b>	<b>95</b>

\*\*The Tuscaloosa VAMC site did not begin randomization until April of 2009 due to the need to complete recruitment of Veterans into the ongoing TVAMC VA Rehabilitation R&D study entitled “The Impact of Vocational Rehabilitation on Veterans with Mental Illness.”

### Recruitment

Prior to admittance into the study, as described by a research team member and documented in the written informed consent, a potential participant was provided with detailed information regarding the study’s sponsor, purpose, procedures, potential risks and benefits, alternative

treatments, compensation, and other required elements. A participant's willingness to take part in the study was documented in the VA medical record. Potential participants were given ample time to consider the informed consent and were allowed to involve family members, significant others and his /her primary treatment team in their decision. Potential participants were informed that refusal to participate in a research protocol will in no way penalize them or change their eligibility for VA services, treatment, or disability payments. All enrolled participants signed an informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization form.

The study's randomization target was 100. Both Bedford and Tuscaloosa met their recruitment goals; Tuscaloosa randomized 33 Veterans and Bedford randomized 34. However, due to turnover in staff, the Birmingham VAMC fell slightly short of goal and randomized 28 Veterans (goal of 34). It was planned for the TVAMC site to make up for this shortfall, but it became impossible to randomize beyond 33 participants due to the freeze on new VRP-TAU intakes because of lack of funding for new transitional work positions. The Bedford site was able to push on and attain an additional randomized veteran; however, due to overall study timelines, enrollment had to end in November 2010. The final total number randomized was 95.

### **Site Visits, Meetings, and Conference Calls**

Study conference calls between all three sites were held monthly to provide status updates and to discuss study-related issues. After February of 2011, the conference calls were reduced to a quarterly basis, however teleconference and on-site supervision of the IPS-SE specialists continued at a greater frequency. Dr. Davis called a meeting of all principal investigators during the International Society of Traumatic Stress Studies Annual Conference held in Atlanta, GA on November 4, 2009. During this meeting, the biostatisticians and the principal investigators, consultants and key staff met to review progress of the study. In 2009 and 2010, the PI and TVAMC Project Manager performed annual site visits at the VAMCs in Tuscaloosa, Birmingham, and Bedford in order to review essential documents, data collection, and discuss staffing and study related issues. A three-site summit was held on April 25<sup>th</sup>, 2010, through a VANTS conference call. The IPS Supervisor and Fidelity Monitor (Toscano) went over the strengths and weaknesses that sites experienced when applying IPS supported employment principles. Although considerable effort had been made, all sites had difficulty integrating their IPS-SE Specialist into the PTSD treatment team due to the large size and complex structure of these treatment teams.

### **IPS Fidelity Monitoring**

Rich Toscano, IPS Supervisor and Fidelity Monitor, conducted quarterly fidelity reviews at each site. Jennie Keleher, MSW, IPS consultant, was retained to provide additional mentoring and training to IPS specialists at each site. She provided weekly guidance through phone calls and email, and weekly conference calls. She visited all sites during the year to provide in-person help with job development and work directly with each IPS specialists' caseload. Turn-over in the IPS staff positions occurred at all three sites at some point during the study, which caused disruption in the delivery of IPS services and continuity of care. The provision of hands-on training by an IPS expert (Keleher and Toscano) eased the transition of the new IPS specialists into their new roles and existing caseloads.

The three domains of fidelity rating to the IPS model are *Staffing Elements*, *Organization Elements* and *Service Elements*. The Staffing elements represent the identification of skilled and trained IPS Specialists to provide the IPS intervention. This is critical to the comprehensive delivery of community-based employer networking and support to the Veterans and the ongoing education of the primary clinical teams within which the IPS Specialist is matrixed. The Organization elements speak to the necessary partnerships with clinical staff to overcome the obstacles presented by the symptoms of PTSD. Optimal implementation reflects the IPS Specialist being assigned to and accepted as a member of the PTSD team. The Service elements are the action steps of hands-on implementation. After initial training & support from the core Vocational Unit, an effective IPS Specialist becomes embedded within the primary PTSD Clinical Team and any works in the community to activate patient-centered job development and employment placement for the Veterans on his/her caseload.

Fidelity monitoring was provided at the three sites from 2009 through 2011 using a validated IPS fidelity rating scale (Bond et al 2012). The IPS fidelity scores fall into three categories of service delivery; 66 – 75 represents GOOD implementation, 56 – 65 represents FAIR implementation and <55 is not considered evidence-based IPS. None of the site exceeded the “fair” rating at any point in the study. The predominant issues impacting fidelity scores were 1) excessive IPS staff turnover resulting in gaps in service, 2) limited integration and investment by the PTSD clinical components, and 3) limited support and involvement from the internal vocational unit. As these areas were addressed in the later part of the study, there was a general increase in the IPS fidelity and greater appreciation for the core elements of the practice at all three sites.

The three sites used their existing PTSD or mental health clinical team configurations and vocational units as a backdrop to the study. The Birmingham VAMC had an established PTSD Clinical Team, whereas, the Tuscaloosa and Bedford VAMCs did not have a cohesive PTSD team to which the IPS Specialist could easily integrate. The Birmingham VAMC PTSD team was extremely busy with large panels of Veterans. The Tuscaloosa VAMC PTSD services were dispersed across the MH Outpatient Clinics. The Bedford VAMC PTSD services reflected a mix of a core PTSD team and some dispersed across the MH Outpatient clinics. The lack of strong, cohesive, integrated PTSD team at the three sites reduced the site’s ability to fully implement the core IPS principles effectively.

Given the limited availability and support from an existing internal Vocational Unit, another core element of the Organization domain, a Mentor-Trainer (Keleher) was added to the national research team to provide training, guidance, supervision, and support to the IPS Specialists at the three research sites midway through the study. The Mentor-Trainer provided teleconference supervision, training and some on-site support to strengthen the IPS Specialists’ actions and strategies for addressing the core practices of the model. Hiring strong IPS candidates with skills and background in the practice also presented challenges to IPS implementation and sustainment. Recruiting personnel with the necessary skills to take on a time-limited research study role reduced the pool of candidates, thus weakening the Staffing Elements in the IPS Fidelity ratings. There were some “pockets of excellence” at all three sites when the IPS Specialist partnered with individual clinicians and the Veteran to activate an individualized, strategic job placement and



support plan, but sustaining such actions across a comprehensive caseload was very challenging, due to the infrastructure issues discussed above.

### **Areas of Challenge that Impacted Recruitment**

The delayed entry into the recruitment phase for the Tuscaloosa site put pressure on this site in order to catch up. In addition, the Vocational Rehabilitation Program at TVAMC went through an extended preparation for site survey by the Commission on Accreditation for Rehabilitation Facilities (CARF), which limited the availability of staff to screen and enroll Veterans for the VRP-TAU services. Because of these factors, staffing of eligible veterans was often postponed, and caused a delay in randomization. IPS specialist turnover proved to be the biggest challenge that was faced across all three sites. The Birmingham VAMC site also experienced turnover in IPS Specialist once and the CRC four times during the course of the study. These staff changes negatively impacted enrollment and end-of-study continuity of care. The Tuscaloosa VAMC experienced turnover in the IPS Specialist twice, which mainly impacted the continuity of care towards the end of the study. The Bedford VAMC faced the loss of their IPS-SE early in the study, which slowed initial enrollment.

## **KEY RESEARCH ACCOMPLISHMENTS**

### **Preliminary VA RR&D Study Accomplished During the Funding Period**

#### **A Randomized Controlled Trial of Supported Employment Among Veterans With PTSD (Davis et al Psychiatric Services 2012; funded by VA RR&D)**

During the funding period, as part of the mission to accelerate research outcomes, the PI (Davis) completed a single-site pilot study to examine the efficacy of IPS in a group of Veterans with PTSD. Unemployed Veterans with PTSD were randomly assigned to IPS (n=42) or a VHA Vocational Rehabilitation Program (VRP) treatment as usual (n=43) and followed for 12 months. TWP was the predominant VRP modality, although some incentive therapy was included. A total of 71 (84%) participants completed the study. Reasons for early exit were withdrawn consent (n=1), relocation (n=3), incarceration (n=2) in IPS group and lost to follow-up (n=2), relocation (n=5), and incarceration (n=1) in VRP. During the 12-month study, 76% of the IPS participants gained competitive employment, compared with 28% of the VRP participants ( $p<.001$ : number needed to treat=2.07). Veterans assigned to IPS also worked substantially more weeks than those assigned to VRP (42% versus 16% of the eligible weeks, respectively;  $p<.001$ ) and earned higher 12-month income. The IPS group achieved competitive employment significantly more quickly than the VRP group (log-rank  $p<.001$ ). Most job acquisition occurred within the first 20 weeks. The outcome of whether or not the participant achieved competitive employment status was an excellent proxy for other occupational outcomes as demonstrated by correlations ranging from 0.53 to 0.79 between occupational outcomes. Additional analysis revealed that 40% (17 of 42) of IPS participants became steady workers, defined as holding a competitive job for  $\geq 50\%$  of the 52-week follow-up, compared to 16% (7 of 43) of those in VRP ( $p=0.01$ ). In conclusion, this study demonstrates feasibility and efficacy of IPS for Veterans with PTSD.

## **The Impact of Supported Employment versus Standard Vocational Rehabilitation for Veterans with PTSD**

This study was a multi-site, 52-week prospective, randomized (1:1) trial to test the efficacy of Individual Placement and Support (IPS), an evidenced-based model of supported employment compared to vocational rehabilitation treatment-as-usual (VRP-TAU) in unemployed Veterans with posttraumatic stress disorder (PTSD). The primary outcome was rates of obtaining a competitive job during the 52-week follow-up phase. Secondary outcomes included number of weeks, days, hours worked, income earned, PTSD symptoms, depressive symptoms, and quality of life.

### **METHODS**

**Inclusion and Exclusion Criteria:** Veterans were included in the study if they were confirmed to have had a lifetime diagnosis of PTSD (confirmed by the MINI International Inventory for Neuropsychiatric Interview); between the ages of 19 to 65 years; eligible for the VAMC VRP-TAU services; currently unemployed; interested in competitive employment; and planning to remain in a 100-mile radius of participating VAMC for the following 12-months. Veterans were excluded if they had a lifetime history of severe traumatic brain injury that had resulted in severe cognitive disorder; a diagnosis of schizophrenia, schizoaffective disorder, or bipolar I disorder (since these individuals are already eligible for IPS-); dementia; immediate need of detoxification from alcohol or drugs; and pending active legal charges with expected incarceration. A history of mild to moderate TBI and all other comorbid Axis I diagnoses, including substance use disorders, bipolar type II, major depression, and other anxiety disorders, were permissible.

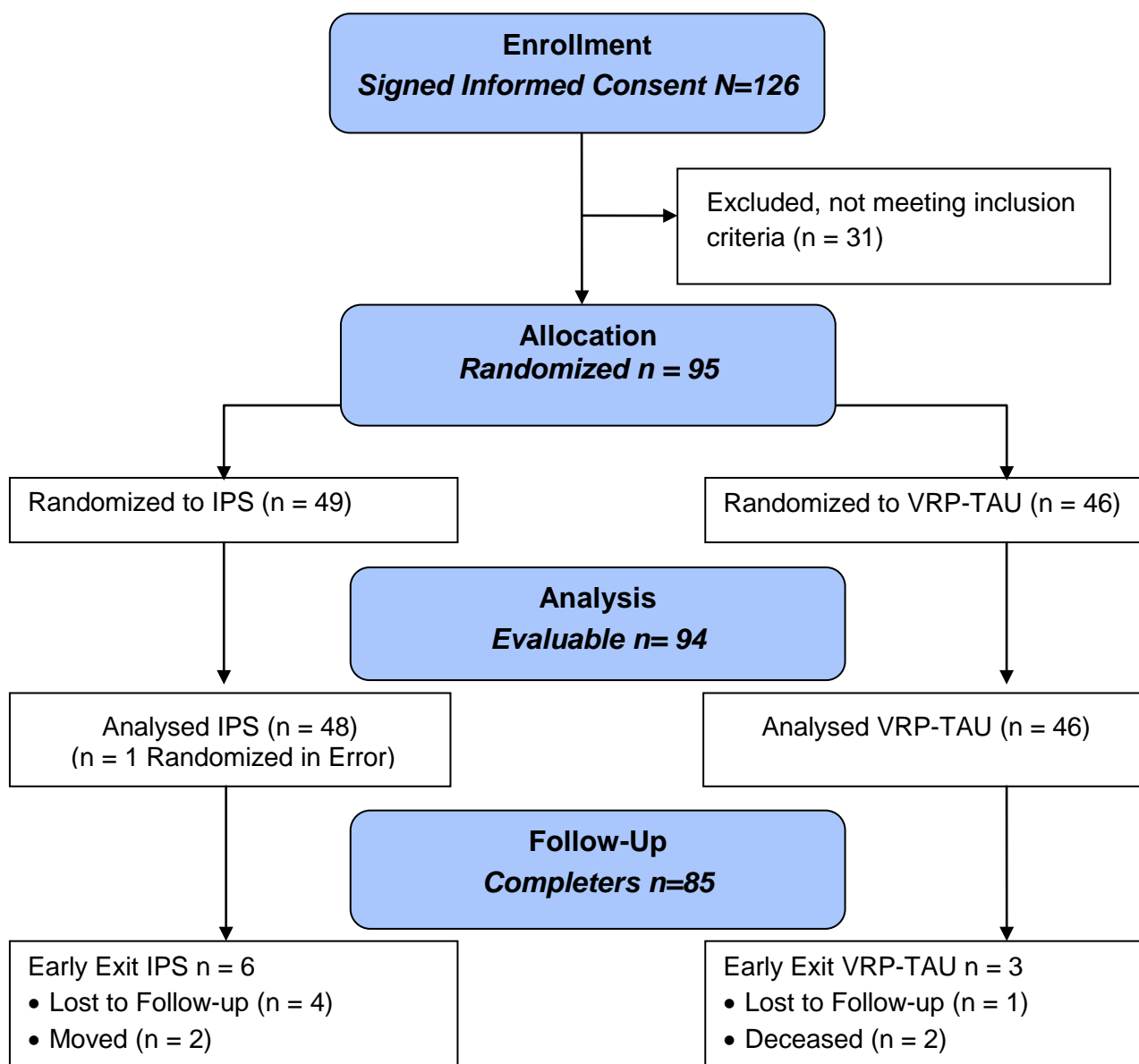
**Assessments:** The MINI International Inventory for Neuropsychiatric Interview (MINI; Sheehan et al 1997)) was assessed at Baseline. The Clinician Administered PTSD Scale (CAPS; Blake et al 1995); Clinical Global Impression – Improvement (CGI-I); Clinical Global Impression Severity (CGI-S); Quality of Life Enjoyment and Satisfaction Questionnaire – Self-report (Q-LES-Q); Quick Inventory of Depressive Symptomatology – Clinician rating 16-item (QIDS-C16); and World Health Organization Disability Assessment Schedule II (WHODAS II) and occupational outcomes were assessed at Baseline (except for CGI-S and Months 1, 2, 3, 4, 6, 8, 10, and 12. A phone contact was made during the interim months 5, 7, 9, and 11 to confirm occupational status and update contact information.

**Statistical Analyses:** The proportion of individuals who obtained a competitive job was compared by treatment group using Fisher's exact test at a two-tailed alpha-level of 0.05. In order to compare this study to other published studies of IPS, other employment outcomes were analyzed for differences between groups. In each case, the IPS group was hypothesized to show greater gains than the VRP-TAU group. These analyses include categorical outcomes (e.g., "yes vs. no" for obtaining competitive employment) and continuous outcomes (e.g., cumulative gross income and weeks/days/hours worked in competitive job). Mean total number of weeks/days/hours worked in a competitive job were compared between groups using a t-test. The mean cumulative gross

income was compared between groups using a *t*-test. The effect of treatment on each of the clinical outcome measures were analyzed using a longitudinal mixed-effects regression model.

**Enrollment, Randomization, and Follow-up:** A total of 126 participants consented and were assessed for eligibility. A total of 95 participants were randomly assigned to either IPS (n=49) or VRP-TAU (n=46). After randomization, it was discovered that one participant was working in a competitive job prior to entry into the study and therefore, was withdrawn from the study and excluded from the analysis (IPS group). A total of 90 participants (96%) completed the one-year follow-up. Reasons for early exit included withdrawn consent (N=4). Figure 1 shows the CONSORT flow for the study.

**Figure 1. CONSORT Flow Diagram for the Randomized Controlled Trial of Individual Placement and Support (IPS) versus Vocational Rehabilitation Program Treatment-as-Usual (VRP-TAU) for Unemployed Veterans with PTSD (All Sites)**



**Adverse Event Monitoring:** Adverse events were evaluated at each visit. All adverse events were recorded at each visit (description, severity, relationship to study, intervention, date onset, date resolution). Regardless of relationship to the study, serious adverse events (as defined by CRF 312.32) were expeditiously reported to the DSMB and IRB.

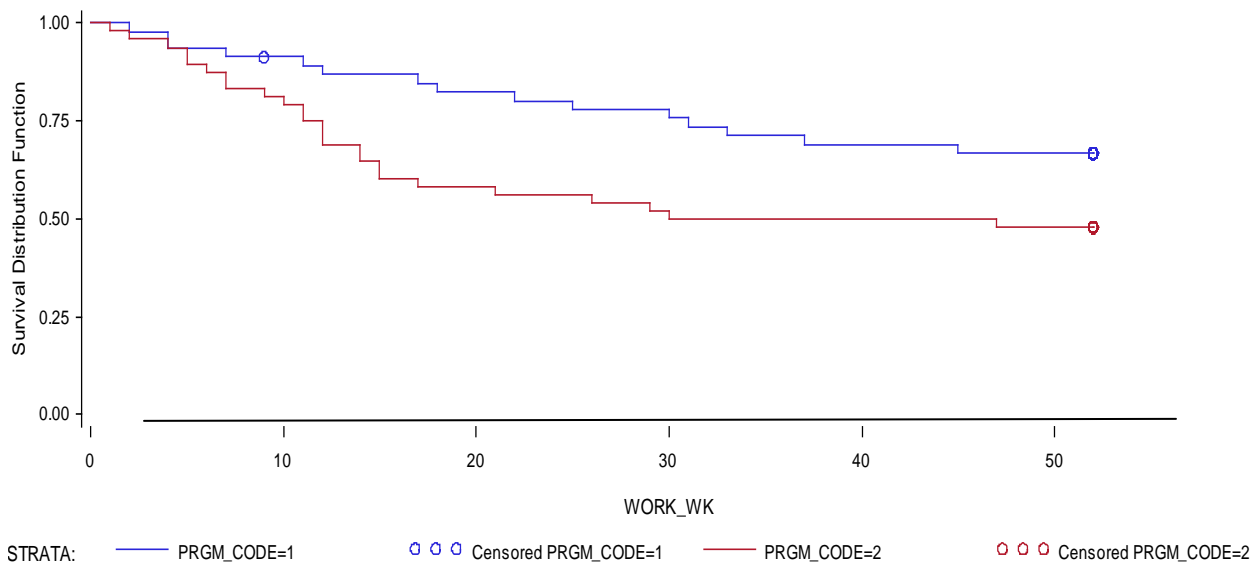
## RESULTS

**Demographics:** The two treatment groups did not differ statistically for any of the demographic conditions including gender, race, marital status, educational attainment, age, or length of military service. The 94 randomized evaluable participants had been unemployed for  $20 \pm 34.7$  months (range of 0–257 months; median of 8 months). In addition to PTSD, the participants had the following axis I disorders: major depressive disorder (n=53, 56%), dysthymia (n=5, 5%), agoraphobia (n=33, 35%), panic disorder (n=20, 21%), social phobia (n=3, 3%), alcohol dependence (n=43, 45%), alcohol abuse (n=12, 13%), and drug dependence (n=5, 5%). The baseline demographic characteristics of the participants are shown in Table 2.

Table 2 – Sociodemographics (n=94)					
Demographic	IPS N=48		VRP N=46		
	N	%	N	%	Test Statistic
<b>Gender</b>					$X^2 = 0.36$
Female	6	13	4	9	0.55
<b>Race/Ethnicity</b>					$X^2 = 2.05$
Caucasian	25	52	25	54	0.56
African American	22	46	20	43	
Native American	0	0	1	2	
Hispanic	1	2	0	0	
<b>Marital Status</b>					$X^2 = 2.46$
Never Married	14	29	10	22	.78
Cohabiting	5	11	3	6	
Married	9	19	9	20	
Separated	7	14	5	11	
Divorced	14	29	14	30	
Widowed	1	2	3	6	
<b>Education</b>					$X^2 = 1.17$
High School	33	6	2	4	0.56
College Degree	34	71	37	80	
Post College	11	23	7	15	
	Mean		Mean		T-Test
Age (yr.)	44.8 +/-11.2		44.5 +/-11.3		t=-0.11
Length of Service (mo.)	6.6 +/-6.0		6.2 +/-5.8		t=-0.29
					p-value

**Primary Outcome:** During the 52-week follow-up, 25 of the 48 IPS participants (52%) gained competitive employment, compared with 15 of the 46 VRP-TAU participants (33%) ( $\chi^2= 3.64$ ,  $df=1$ ,  $p=.056$ ). That is, Veterans with PTSD who participated in IPS were 1.7 times more likely to gain competitive employment than those who received VRP-TAU. The number-needed-to-treat (NNT) was 5.26. The IPS and VRP-TAU participants worked in a competitive job an average of 23% and 13% of the eligible weeks, respectively (Mann-Whitney z test,  $p=0.10$ ). Table 3 shows that there were no statistically significant between-group differences in terms of number of weeks, days, or hours worked, or the amount of income earned. Figure 2 illustrates the time until first competitive job for each group. The IPS group gained competitive employment significantly faster than VRP-TAU (log-rank  $\chi^2= 4.25$ ,  $p=0.04$ ). Most job acquisition in IPS occurred within the first 25 weeks.

Table 3. Occupational Outcomes					
Outcomes at 1 Year	IPS (n=48)	VRP-TAU (n=46)	Cohen		CI
	Mean ±SD	Mean	P	d	95%
Weeks Competitively Employed	11.8 ±15.6	6.8 ±13.6	0.0949	-0.34	-0.07, 0.76
Days Competitively Employed	89.2 ±68.4	92.1 ±84.1	0.9056	-0.03	-0.45, 0.37
Hours Competitively Employed	736.8 ±635.2	695 ±662.1	0.8438	0.06	-0.35, 0.48
Income \$ (Competitive)	8522 ±9458	8422 ±7769	0.9727	0.01	-0.40, 0.42



**FIGURE 2. Weeks until Participant Gained Competitive Employment as Illustrated by Kaplan Meir Survival Curve. IPS Participants gained competitive employment more quickly than those in VRP-TAU (p=0.0392). Program 1 (Blue) = VRP-TAU; Program 2 (Red) = IPS**

**Clinical Outcomes:** As shown in Table 4, there were no between group differences in outcomes in regard to CAPS, QIDS-CR16, CGI-S, DTS, and WHODAS (month 2 not shown due to space).

**Table 4. Clinical Assessments in Veterans with PTSD randomized to VRP-TAU or IPS**

Assessment	Baseline Mean $\pm$ SD	Month 4 Mean $\pm$ SD	Month 6 Mean $\pm$ SD	Month 8 Mean $\pm$ SD	Month 10 Mean $\pm$ SD	Month 12 Mean $\pm$ SD
<b>CAPS</b>						
VRP-TAU	75.97 $\pm$ 18.1	62.6 $\pm$ 27.4	63.4 $\pm$ 27.5	55.7 $\pm$ 30.9	59.8 $\pm$ 30.0	56.7 $\pm$ 31.4
IPS	73.71 $\pm$ 18.9	63.5 $\pm$ 28.8	60.1 $\pm$ 25.7	63.4 $\pm$ 28.7	61.5 $\pm$ 29.5	61.35 $\pm$ 33.5
<b>QIDS-CR</b>						
VRP-TAU	10.3 $\pm$ 4.6	9.1 $\pm$ 5.0	8.7 $\pm$ 5.8	9.7 $\pm$ 5.8	8.9 $\pm$ 4.8	8.4 $\pm$ 4.9
IPS	10.4 $\pm$ 4.6	10.0 $\pm$ 4.4	9.3 $\pm$ 5.7	9.3 $\pm$ 5.7	8.5 $\pm$ 5.3	8.9 $\pm$ 5.7
<b>CGI-S</b>						
VRP-TAU	4.7 $\pm$ 0.8	3.6 $\pm$ 1.8	3.8 $\pm$ 1.5	3.8 $\pm$ 1.3	3.3 $\pm$ 1.7	3.5 $\pm$ 1.5
IPS	4.7 $\pm$ 0.8	4.1 $\pm$ 1.3	3.8 $\pm$ 1.4	4.0 $\pm$ 0.6	3.9 $\pm$ 1.6	3.9 $\pm$ 1.5
<b>DTS</b>						
VRP-TAU	75.4 $\pm$ 30.4	68.6 $\pm$ 33.3	65.9 $\pm$ 33.9	58.5 $\pm$ 38.2	61.5 $\pm$ 38.4	60.5 $\pm$ 36.2
IPS	74.9 $\pm$ 28.4	69.7 $\pm$ 31.2	67.2 $\pm$ 27.5	70.0 $\pm$ 31.1	68.5 $\pm$ 34.1	68.5 $\pm$ 34.3
<b>WHODAS II</b>						
VRP-TAU	70.0 $\pm$ 19.3	69.4 $\pm$ 25.4	69.6 $\pm$ 26.1	66.0 $\pm$ 22.8	70.9 $\pm$ 26.0	69.8 $\pm$ 26.1
IPS	72.3 $\pm$ 22.3	71.6 $\pm$ 23.6	68.7 $\pm$ 24.7	72.9 $\pm$ 23.2	72.0 $\pm$ 23.2	73.7 $\pm$ 24.1

## REPORTABLE OUTCOMES

### Poster Presentations

1. Davis LL, Yang s, Kyriakides T, Guarino P, Toscano R, Resnick S, Mueller L, Blansett C, Drake R. A Recovery Model Illustrated by the Methodology of a VA Cooperative Study Program. The International Society of Clinical Trials Methodology (ISCTM) Annual Meeting; Oct 2, 2013; Philadelphia, PA.
2. Davis LL, Parker PE, Drebing C, Blackburn L, Blansett CM, Perry B, Mueller L, Hemphill T, Washington K, Toscano R, Bartolucci A, Leon A. The Impact of Supported Employment versus Standard Vocational Rehabilitation in Veterans with PTSD." International Society of Traumatic Stress Studies (ISTSS) Annual Meeting; Nov 4, 2009; Atlanta, GA.

### Oral Presentations

1. Davis LL. Preliminary Findings of Employment Outcomes from a Recent Multisite, Randomized Controlled Trial of Supported Employment for Veterans with Post-Traumatic Stress Disorder. The International Society of Traumatic Stress Studies Annual Meeting; Nov 7, 2013; Philadelphia, PA.
2. Davis LL. Individual Placement and Support in Veterans with Posttraumatic Stress Disorder. Johnson & Johnson-Dartmouth Community Mental Health Supported Employment Program Annual Meeting; June 5, 2013; Madison, WI.

3. Davis LL. From the Detection and Diagnosis to the Prevention and Treatment of Posttraumatic Stress Disorder. American Society of Clinical Psychopharmacology NCDEU; May 28, 2013; Hollywood, FL.
4. Davis LL. Individual Placement and Support Supported Employment for Veterans with PTSD: Results from Pilot Study. Department of Psychiatry Grand Rounds. Weill Medical College of Cornell University; Feb 15, 2012; New York, NY.
5. Davis LL. Individual Placement and Support Supported Employment for Veterans with PTSD. International Society of Traumatic Stress Studies Annual Meeting; Nov 4, 2011; Baltimore, MD.
6. Davis LL, Drebing C, Parker P, Leon, AC. Occupational Recovery in Persons with PTSD: Results from Clinical Investigations; International Society for Traumatic Stress Studies Annual Meeting; Nov 5, 2010; Montreal, Canada.
7. Davis LL, Leon AC. The Role and Interpretation of Pilot Studies in PTSD Intervention Research. International Society for Traumatic Stress Studies; Nov 6, 2010; Montreal Canada.
8. Davis LL, Toscano R, Parker PE, Hemphill T, Washington K. Supported Employment Vocational Rehabilitation for Veterans with Posttraumatic Stress Disorder; Anxiety Disorders Association of America 30<sup>th</sup> Annual Conference; March, 2010, Orlando, FL.
9. Davis, LL. Advancing Research Standards and Testing Novel Treatments for Posttraumatic Stress Disorder. University of Alabama at Birmingham Department of Psychiatry Grand Rounds; Jan 5, 2010; Birmingham, AL.
10. Davis LL, Leon AC, Hamner M, Heinssen R. Accelerating the Pace for Clinical Trials in Posttraumatic Stress Disorder: Priorities and Guidelines for Clinical Trial Methodology. Presentation at: NIMH New Clinical Drug Evaluation Unit (NCDEU) Annual Meeting; June, 2009; Hollywood, FL.
11. Davis LL, Suris A, Leon AC, Neylan T, O'Leary T. Clinical Trials Methodology in PTSD. International Society of Clinical Trials Methodology conference; March, 2009; Washington, DC.
12. Davis LL, Leon AC, Suris A, Neylan T. Improving Methodology of Randomized Clinical Trials in PTSD. Panel Symposium. International Society of Clinical Trial Methodology 5th Annual Scientific Meeting. March 4, 2009; Washington, DC.
13. Davis LL, Leon AC, Hamner M. Reinventing the wheel in clinical trial design. European Congress of Psychiatry Annual Meeting; Jan 28, 2009; Lisbon, Portugal.
14. Davis LL, Drebing C, Newell J, Riley A, Toscano R. Supported employment in Veterans with PTSD. International Society of Traumatic Stress Studies. Nov 14, 2008; Chicago, IL.

### **Paper submitted, rejected, now under revision**

1. Advancing Individual Placement and Support to Veterans with Posttraumatic Stress Disorder. Proposed Co-authors: Davis L, Resnick S, Suris A, Mueller L, Ottomanelli L, Rehmert A, Drake R, Kyriakides T, Blansett C, Toscano R, Yang S, Guarino P, and CSP #589 Investigators. This article describes the rationale, methods and operations of the VA Cooperative Studies Program (CSP #589).

### **Manuscripts Related to Award**

1. **Davis LL**, Leon AC, Toscano R, Drebing CE, Ward LC, Parker PE, Kashner TM, Drake RE. A randomized controlled trial of supported employment among veterans with post-traumatic stress disorder. *Psychiatric Services*. 2012;663(5):464-470.

### **Manuscripts by Partnering PIs Indirectly Related to Award**

1. **Davis LL**, Pilkinton P, Poddar S, Blansett C, Toscano R, Parker PE. Impact of social challenges on gaining employment for veterans with posttraumatic stress disorder: an exploratory moderator analysis. *Psychiatr Rehabil J*. 2014;37(2):107-9.
2. **Drebing CE**, Bell M, Campinell EA, Fraser R, Malec J, Penk W, Pruitt-Stephens L. Vocational services research: recommendations for next stage work. *J Rehabil Res Dev*. 2012;49(1):101-19.
3. **Drebing CE**, Mueller L, Van Ormer EA, Duffy P, LePage J, Rosenheck R, Drake R, Rose GS, King K, Penk W. Pathways to vocational services: factors affecting entry by veterans enrolled in Veterans Health Administration mental health services. *Psychol Serv*. 2012;9(1):49-63.
4. Leon AC, **Davis LL**, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res*. 2011;45(5):626-9.
5. Leon AC and **Davis LL**. Enhancing clinical trial design of interventions for posttraumatic stress. *J Trauma Stress*. 2009;22(6):603-11.
6. O'Connor MK, Mueller L, Van Ormer A, Drake R, Penk W, Rosenheck R, Semiatin A, **Drebing CE**. Cognitive impairment as barrier to engagement in vocational services among veterans with severe mental illness. *J Rehabil Res Dev*. 2011;48(5):597-608.
7. Penk W, **Drebing CE**, Rosenheck RA, Krebs C, Van Ormer A, Mueller L. Veterans Health Administration Transitional work experience vs. job placement in veterans with co-morbid substance use and non-psychotic psychiatric disorders. *Psychiatr Rehabil J*. 2010;33(4):297-307.



## OTHER REPORTABLE OUTCOMES

### Applications Funded

#### **1. Veterans Individual Placement and Support Towards Advancing Recovery (VIP-STAR);** Study Chair: Lori Davis, MD. VA Cooperative Study Program (CSP#589)

The objectives of this multi-site CSP study are to test the effectiveness of IPS compared to VA Transitional Work Programs (TWP) in the recovery of Veterans with PTSD and to learn more about IPS impact on PTSD symptoms, self-esteem, quality of life, PTSD-related functional outcomes, and health outcomes in a large geographic and urban-rural diverse Veteran population. The proposed study will randomize 540 participants at twelve VA sites over one year and follow each participant for 18 months. As the primary outcome, the two groups will be compared in terms of the proportion of study participants who meet the definition of steady worker, i.e. hold competitive employment for at least 50% of the 18-month follow-up period. Competitive employment is defined as a job receiving regular wages in a setting that is not set aside, sheltered, or enclaved, that is, the same job could be held by people without a mental illness or disability and is not a set-aside job in the TWP program. Secondary outcomes will include change in other occupational outcomes, PTSD symptoms, self-esteem, quality of life, and PTSD-related functioning. We will explore the differences between groups in terms of occurrences of negative health outcomes. These findings would provide generalizable evidence of the effectiveness of differing employment support to the VHA stakeholders who inform policy and service delivery for Veterans with PTSD. Given the number of Veterans with PTSD, it is of critical importance for the VA to offer employment service programs based on the best evidence-based recovery orientated model for this group. Conducting a large multisite study is the next logical step in confirming IPS as an evidence-based employment service program for Veterans with PTSD.

#### **2. Moderator Effects of Psychosocial Domains on Individual Placement and Support (IPS) Supported Employment (SE) Vs. Standard Vocational Rehabilitation Program (VRP) for PTSD.** Principal Investigator: Lori L. Davis, MD; Coinvestigators: Andrew C. Leon, PhD & Charles Drebing, PhD. VA Rehabilitation Research and Development. 2010-2011.

The goal of this study was to conduct a post-hoc exploratory moderator analysis on the single-site randomized controlled study of IPS versus VRP-TAU in Veterans with PTSD (RR&D Merit; PI Davis). The baseline characteristics of interest were housing, transportation, financial means, and family care burden. When examining groups within each moderator, there was a greater IPS supportive employment benefit in gaining competitive employment for those with inadequate transportation (NNT=1.5) and inadequate housing (NNT 1.5) compared to the main finding of the pilot study (NNT 2.07). Compared to the main finding of the pilot study, there was no greater advantage of IPS for those with adequate transportation (NNT = 2.4) or adequate housing (NNT = 2.4). Compared to the main finding in the pilot study, those without a family care burden had a greater benefit from IPS (NNT 1.4) and those with family care burden had a reduced treatment effect (NNT 3.3). These results are exploratory and are not intended to guide clinical decision-making, but rather offer a potentially useful strategy in the design of larger trials of IPS.

## **Applications Pending**

### **1. Efficacy of Supported Employment within the OIF/OEF Patient Aligned Care Team**

PI: Lori Davis, MD; VA Rehabilitation Research and Development Merit Award; Submitted June 2014.

This study is a single site, prospective, randomized, controlled trial that evaluates the efficacy of IPS when delivered within a primary care Patient Aligned Care Team (PACT) designated for Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn (OEF/OIF/OND) Veterans. Participants will be OEF/OIF/OND Veterans receiving care in the PACT who are currently unemployed and have a disabling or potentially disabling Axis I diagnosis, other than a serious mental illness and will be randomized 1:1 to either IPS or the VHA standard of care called Transitional Work Program. Compared to Transitional Work Program (control condition), IPS delivered within a PACT is hypothesized to result in a higher rate of steady workers, as defined by working  $\geq 50\%$  of the weeks in the 12-month follow-up period in a competitive job (primary); quality of life, and self-esteem (secondary), improved community re-integration (exploratory), improved psychiatric symptoms (exploratory), and lower rates of high intensity crisis events/services (exploratory). In addition, IPS delivered within a PACT will be feasible and yield very good Veteran satisfaction. In an innovative approach, this study breaks from the diagnostic categorical approach and the mental health treatment setting and evaluates the efficacy of IPS when delivered in a primary care setting, specifically a PACT that serves Veterans who have returned from the Iraq or Afghanistan conflicts. Making a substantial paradigm shift, this study will integrate IPS within a PACT for the first time ever.

### **2. PTSD and Supported Employment: A Qualitative Evaluation of Return to Steady Work.**

Co-Principal Investigators: Lisa Zubkoff and Lori Davis. VA Rehabilitation R&D Merit Award; Submitted June 2014.

The goal of this qualitative study is to understand 1) the experiences of Veterans with PTSD as they participate in an IPS supported employment rehabilitation program, 2) the impact of PTSD symptoms within the context of seeking or sustaining competitive employment, and 3) the facilitating or impeding elements of successful return to steady work. Specifically, this project will seek to gain knowledge about the reasons why some IPS participants with PTSD are able to attain and maintain employment while others are not. Participants will be a sample of Veterans enrolled in VA's CSP #589 study and receiving IPS services. Interviews with Veterans will explore the experiences of Veterans to determine factors that may influence gaining or maintaining successful employment. Interviews with VA IPS staff will inquire about their perspective on the challenges Veterans with PTSD face with employment. The proposed research will employ qualitative methods using semi-structured interviews with Veterans and VA IPS staff. We will invite all 12 of the CSP #589 sites to participate in this study. Individual interviews with Veterans and IPS specialists will inquire about: (1) first person perspectives of Veterans with PTSD about experiences with employment services (IPS) as well as experiences seeking, obtaining, and maintaining competitive employment; (2) the perspectives of VA staff delivering IPS services, (3)

insights into why IPS succeeds, fails, or is selectively successful in the target population; and (4) potential strategies to tailor IPS for the target population. Individual semi-structured interviews with VA IPS staff at participating sites will consist of open-ended questions to inquire into their subjective experiences, to include: (1) attitudes toward providing vocational services to Veterans with PTSD; (2) key challenges of providing vocational services to this population; (3) strategies to overcome challenges; (4) barriers to and facilitators of obtaining competitive employment among Veterans with PTSD and (5) how IPS services could be better tailored to meet the needs of Veterans with PTSD. Interviews will be audio-recorded and transcribed.

### **Applications Not Funded**

1. **The Impact of PTSD on Occupational Functioning and Recovery.** Co-Principal Investigators: Lisa Zubkoff and Lori Davis. VA Rehabilitation Research and Development Small Projects in Rehabilitation Research (SPIRE) Application. Submitted June and Dec 2013.

The goals and specific objectives of the proposed research are to explore the impact of posttraumatic stress disorder (PTSD) on occupational functioning and recovery in Veterans with PTSD who are initially unemployed and currently participating in the VA Cooperative Study Program #589 study comparing Individual Placement and Support (IPS), a model of supported employment to VA Transitional Work Program (TWP).

### **Licenses applied for and/or issued**

None

### **Degrees obtained that are supported by this award**

1. Jason Newell, Clinical Research Coordinator (Tuscaloosa) earned a Doctorate in Psychology while working on this study. He obtained a position as Assistant Professor at the University of Montevallo, Montevallo, Alabama
2. Kelly Dvorin, Clinical Research Coordinator (Bedford) earned a Doctorate in Psychology while working on this study.
3. Lisa Mueller, PhD, Clinical Research Coordinator (Bedford) received a VA Rehabilitation R&D Career Development Award during the course of this study award period.

## CONCLUSION

Veterans' ability to obtain and maintain gainful employment is essential to successful reintegration into civilian life. Veterans returning from the Gulf War-era II conflicts, defined as having served in the military since Sept 2001, often experience a potentially disabling medical or mental condition and confront unemployment upon their military discharge. The current VA vocational rehabilitation programs do not sufficiently meet the employment rehabilitation needs of Veterans with disabilities, especially PTSD. For example, a VA Northeast Program Evaluation Center (NEPEC) study evaluating administrative data of 5,862 Veterans from 122 Compensated Work Therapy (CWT) programs, found that the rate of competitive employment at discharge was only 30% for Veterans with PTSD and 36% for those without PTSD, leaving the majority unemployed (Resnick and Rosenheck 2008). Serving as the first study in a PTSD population, our single site pilot study found superior outcomes from IPS compared to the conventional VA VRP-TAU in unemployed Veterans with PTSD (n=85).<sup>1</sup> During the 12-month study follow-up period, 76% of the Veterans with PTSD randomized to IPS gained competitive employment, compared to 28% of those randomized to VRP-TAU (Davis et al 2012).

Although the primary outcome of achieving competitive employment still favored IPS, the results were not as striking in the three-site USAMRMC-funded study. Of the 94 randomized Veterans with PTSD, 52% of the IPS participants gained competitive employment compared to 33% of the 46 VRP-TAU participants ( $\chi^2= 3.64$ ,  $df=1$ ,  $p=.056$ ). That is, Veterans with PTSD who participated in IPS were 1.7 times more likely to gain competitive employment than those who received VRP-TAU. The number-needed-to-treat (NNT) was 5.26. The IPS and VRP-TAU participants worked in a competitive job an average of 23% and 13% of the eligible weeks, respectively (Mann-Whitney z test,  $p=0.10$ ). Table 3 shows that there were no statistically significant between-group differences in terms of number of weeks, days, or hours worked, or the amount of income earned. The IPS group gained competitive employment significantly faster than VRP-TAU (log-rank  $\chi^2= 4.25$ ,  $p=0.04$ ). Most job acquisition in IPS occurred within the first 25 weeks.

The outcomes seen in the VRP-TAU group is consistent with national averages; approximately one-third of Veterans with PTSD obtain competitive employment after participating in VRP-TUA. The outcomes seen in the IPS group is below those found in previous studies. Previous studies have shown that two-thirds or more of persons engaged in IPS obtain competitive employment.

Strengths of this study include the multi-site approach, randomized design, and rigorous fidelity monitoring of the IPS delivery. Limitations of this study include the small sample size, fair implementation of IPS across sites during the first half of study implementation, difficulty integrating the IPS services within the PTSD and mental health clinical teams, and reduced continuity of care due to IPS specialist staff turn-over during the study.

In conclusion, the pilot VA RR&D and multi-site USAMRMC studies provided the experience and requisite data to justify the multi-site study funded by VA Cooperative Studies Program (i.e. CSP#589). Beginning December 2013, the CSP study began prospectively randomizing

unemployed Veterans with PTSD into a multisite clinical trial to evaluate the effectiveness of IPS compared to VA Transitional Work Programs (n=540).

The results of the forthcoming VA CSP study will ultimately inform VA stakeholders and help in their decision on whether to expand the target population for IPS to Veterans with PTSD. This expansion would require a major adaptation to CWT programming and personnel, and so clear substantial evidence is needed to support such a dramatic change. Such modifications in the VA practice could substantially improve Veteran rehabilitation outcomes, moving a significantly greater number of disabled Veterans back to full and productive lives in the community. Given the large influx of OIF/OEF/OND Veterans seeking services and the potential chronic course that is predicted for many of them with a mental health issue, an improved employment and reintegration success rate will have a dramatic effect on the future functioning of this large cohort of young Veterans. An intervention, such as IPS, that directly addresses the occupational recovery of Veterans has the potential to improve Veterans' personal income, clinical outcome, and quality of life, while offsetting VA disability costs and increasing the US income tax revenue. The outcomes of this CSP study may lead to a shift in rehabilitation services within the VHA and improve the lives of thousands of Veterans who would otherwise have difficulty with reintegration and be pushed to the unhealthy and dangerous margins of society.

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## **APPENDICES:**

**Davis LL**, Leon AC, Toscano R, Drebing CE, Ward LC, Parker PE, Kashner TM, Drake RE. A randomized controlled trial of supported employment among veterans with post-traumatic stress disorder. *Psychiatric Services*. 2012;663(5):464-470.

# A Randomized Controlled Trial of Supported Employment Among Veterans With Posttraumatic Stress Disorder

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**Objective:** Posttraumatic stress disorder (PTSD) is a potentially disabling mental illness that can cause occupational dysfunction. Although vocational rehabilitation is often prescribed for patients with PTSD, standard vocational services are far from adequate in helping them obtain and maintain competitive employment. This study is the first to examine the outcome of evidence-based supported employment for veterans with PTSD. **Methods:** Unemployed veterans with PTSD were randomly assigned to either individual placement and support (IPS) supported employment (N=42) or a Veterans Health Administration Vocational Rehabilitation Program (VRP) treatment as usual (N=43). Employment rates and occupational outcomes were followed for 12 months. **Results:** During the 12-month study, 76% of the IPS participants gained competitive employment, compared with 28% of the VRP participants (number needed to treat=2.07;  $\chi^2=19.84$ ,  $df=1$ ,  $p<.001$ ). Veterans assigned to IPS also worked substantially more weeks than those assigned to VRP (42% versus 16% of the eligible weeks, respectively; Mann-Whitney  $z$  test  $p<.001$ ) and earned higher 12-month income (mean $\pm$ SD income of \$9,264 $\pm$ \$13,294 for IPS versus \$2,601 $\pm$ \$6,009 for VRP; Mann-Whitney  $z$  test  $p<.001$ ) during the 12-month period. **Conclusions:** Veterans with PTSD who received IPS were 2.7 times more likely to gain competitive employment than those who received VRP. Because work is central to recovery, these results should assist stakeholders in planning improved services for veterans with PTSD. (*Psychiatric Services* 63:464–470, 2012; doi:10.1176/appi.ps.201100340)

Posttraumatic stress disorder (PTSD) is the most common psychiatric condition for which veterans seek disability compensation from the Department of Veterans Affairs (VA). Although most veterans with PTSD have some college education, few have jobs, almost 40% are impoverished, and most have lower scores on measures of work role and social functioning than people with serious mental illness (that is, bipolar I disorder, schizophrenia, schizoaffective disorder, other psychotic disorder, or major depressive disorder with psychotic features) (1).

According to a 2011 report from the U.S. Department of Labor, the 2010 unemployment rates were 11.5% for Gulf War-era II veterans, 21% for Gulf War-era II veterans with service-connected disabilities, 13% for all service-connected veterans of all eras combined and 9.4% for nonveterans (2). Veterans of Gulf War era II include all those who served in the military since September 2001, which includes those serving in Operation Enduring Freedom and Operation Iraqi Freedom. The unemployment rates for civilians with PTSD and veterans with PTSD are much higher than the rates for the civilian and veteran general population (3). According to a recent VA Northeast Program Evaluation Center report, 61% of veterans (N=11,647) entering specialized out-

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Dr. Davis and Mr. Toscano are affiliated with the Research and Development Service and Dr. Ward is with the Psychology Service, all at the Tuscaloosa Veterans Affairs Medical Center (VAMC), 3701 Loop Road East, Tuscaloosa, AL 35404 (e-mail: lori.davis@va.gov). The late Dr. Leon was with the Department of Psychiatry, Weill Cornell Medical College, New York. Dr. Drebing is with the Department of Psychiatry, Boston University School of Medicine, and with the New England Mental Illness Research, Education and Clinical Center, Edith Nourse Rogers Memorial Veterans Hospital, Bedford, Massachusetts. Dr. Parker is with the Mental Health Service, VAMC, Birmingham, Alabama. Dr. Kashner is with the Office of Academic Affiliations, U.S. Department of Veterans Affairs, Washington, D.C., and with Loma Linda University School of Medicine, Loma Linda, California. Dr. Drake is with the Psychiatric Research Center, Dartmouth Medical School, Lebanon, New Hampshire.



patient PTSD programs were not working (26% were retired, 22% were completely disabled, 27% were unable to find work, and 25% were not looking for work) (4).

Among veterans with PTSD, seeking disability compensation has not adversely affected clinical outcomes (5,6). However, disability compensation programs for veterans have appeared to discourage full participation in vocational rehabilitation programs, which has resulted in poorer rehabilitation outcomes (7).

Prior randomized trials have shown that compensated work therapy through Veterans Health Administration (VHA)-contracted industries had initially positive but declining effects on addiction outcomes and episodes of homelessness and incarceration (8). In a Northeast Program Evaluation Center study evaluating electronic data for 5,862 veterans from 122 compensated work therapy programs (9), veterans with PTSD were 19% less likely to be employed at discharge from the VHA compensated work therapy program than those without a diagnosis of PTSD (that is, 30% and 36% employed, respectively). Veterans with PTSD involved in compensated work therapy were no more likely to be employed at four-month follow-up than those who participated in a specialized PTSD treatment program (10). Thus the standard VA Vocational Rehabilitation Program (VRP) does not meet the occupational recovery needs of veterans with PTSD.

Individual placement and support (IPS) supported employment is an evidence-based vocational rehabilitation model that has been shown to improve occupational and rehabilitation outcomes for people with severe and persistent mental illness, but few participants with a primary diagnosis of PTSD have been included in previous studies (11–15). Engaging in competitive employment, rather than in sheltered jobs, has been shown to enhance other recovery outcomes, such as self-esteem and quality of life, among people with serious mental illness (16).

The impact of IPS supported employment for individuals with a primary diagnosis of PTSD has not been

studied. Our study specifically addressed this gap in the field of rehabilitation research. We hypothesized that participants assigned to IPS would have a higher competitive employment rate than their counterparts assigned to VRP. A secondary hypothesis postulated that those assigned to supported employment would work competitively for a higher proportion of eligible weeks than those assigned to VRP.

## Methods

### Participants

From 2006 to 2010, veterans with PTSD at the Tuscaloosa VA Medical Center (VAMC) were enrolled in a 12-month, prospective randomized comparison of IPS and VRP. This study (www.ClinicalTrials.gov identifier number NCT00333801) was approved by the Tuscaloosa VAMC Institutional Review Board. A trained investigator or clinical research coordinator explained all study procedures, alternatives to participation, and potential benefits and risks to prospective participants and obtained their written informed consent before study enrollment. Veterans were eligible for the study if they had a diagnosis of PTSD, were aged 19 to 60, were eligible for the Tuscaloosa VAMC VRP (that is, had a medical clearance that they were able to participate in a work activity; work restrictions had to be noted, if present), were currently unemployed, were interested in competitive employment, and were planning to remain in a 100-mile radius of the Tuscaloosa VAMC for the 12-month duration. Veterans were excluded if they had a lifetime history of severe traumatic brain injury that resulted in severe cognitive disorder; a diagnosis of schizophrenia, schizoaffective disorder, or bipolar I disorder (because these individuals are already eligible for IPS); a diagnosis of dementia; immediate need of detoxification from alcohol or drugs; or pending active legal charges with expected incarceration. A history of mild to moderate traumatic brain injury and all other comorbid axis I diagnoses, including substance use disorders, bipolar disorder type II, major depression, and other anxiety disorders, were permissible.

## Interventions

Both interventions operated under the VHA Compensated Work Therapy program. The final goal for both interventions was competitive employment, although the methods and pathways were different. Table 1 provides an overview of the interventions and the differences between them. The IPS intervention involved several important features. Eligibility was based on the participant's choice and interest in competitive work. The IPS specialist was integrated into the clinical mental health or PTSD treatment team, carried out all phases of the vocational services, provided predominantly community-based services, provided assertive engagement and outreach in community-based employment, had a caseload of no more than 25 clients, and provided continuous, time-unlimited, follow-along supports for vocational services. IPS involved rapid job search and individualized placement in diverse competitive jobs, with ongoing work-based vocational assessment and assistance in finding subsequent jobs, if needed. Group supervision is regularly scheduled with IPS specialists and an IPS supervisor. The IPS model is described in *A Working Life for People With Severe Mental Illness* (17) and an IPS manual from the Substance Abuse and Mental Health Services Administration (18). These references served as the study's manuals for IPS.

VRP followed the standard care in place at the Tuscaloosa VAMC, which included one or more of these components: routine prevocational testing and evaluation for all patients on referral to VRP, vocational rehabilitation therapy that provided a work regimen with monetary incentives derived from contracts whereby participants are paid on a piece-rate basis related to their production, and a transitional work program that included a temporary work experience (that is, time limited) either within the Tuscaloosa VAMC or in community settings (called the transitional work external or transitional work experience). The VRP model featured a VRP specialist who carried out some, but not all, phases of the vocational service; provided some community-



**Table 1**

Comparison of the Veterans Health Administration Vocational Rehabilitation Program (VRP) and individual placement and support (IPS)<sup>a</sup>

Domain	VRP	IPS
Staffing		
Caseload per specialist	30 or more clients	25 or fewer clients
Vocational services	Specialist provides traditional non-supported employment vocational services (set-aside temporary jobs)	Specialist provides only IPS services (obtaining and maintaining a competitive job)
Vocational functions	Specialist maintains caseload but refers clients to other programs for vocational services (that is, career centers)	Specialist carries out all phases of vocational service (job search and placement, ongoing support and follow-up).
Organization		
Integration of vocational services with mental health treatment team	Specialist is part of a VRP that is separate from mental health treatment and has little or no regular direct contact with the mental health treatment team	Specialist is attached and integrated with one or more members of the mental health treatment team
Vocational unit	Specialists may or may not be part of a unit; specialists may or may not meet as a group	Specialists form a vocational unit with group supervision at least weekly
Exclusion criteria	Clients are screened out on the basis of job readiness, limited functioning, or other reason	All clients are encouraged to participate, and there are no exclusion criteria
Ongoing, work-based assessment	Vocational evaluation is conducted before job placement with emphasis on office-based assessments	Vocational assessment is ongoing and occurs in community jobs rather than being office based or via a battery of tests
Competitive job search	First contact with employer about a competitive competitive job is delayed several months after entry	First contact with employer about a competitive job is typically within one month after entry
Individualized job search	Decisions are usually driven by the nature of the job market and the availability of set-aside jobs	Employer contacts are based on job choices that reflect clients' preferences and strengths
Diversity of jobs	There is little diversity, and set-aside jobs are usually entry level	There is broad diversity; jobs are varied entry level and community based
Permanence of jobs developed	Specialists usually do not provide options for permanent, competitive jobs	Virtually all of the competitive jobs offered by specialists are permanent
Jobs as transitions	Specialists prepare clients for one job and, if it ends, they do not necessarily help clients find another	Specialists help clients end jobs when appropriate and offer to help clients find other jobs
Follow-along supports	Follow-along supports are either nonexistent or time limited	Most working clients are provided flexible follow-along supports that are individualized and ongoing
Community-based	Specialists spend less than 10% of their time in the community	Specialists spend 70% or more of their time in the community
Assertive engagement and outreach	Specialists do not provide outreach to clients as part of initial engagement or to those who stop attending the vocational service	Specialists provide outreach as part of initial engagement and at least monthly on a time-unlimited basis when clients stop attending the vocational service

<sup>a</sup> The domains for comparison are from the Supported Employment Fidelity Scale (26).

based services (if a temporary work setting was external to VAMC), provided time-limited job search assistance to help the client obtain competitive employment, and had no maximum caseload. VRP had an initial short-term set-aside of transitional work experiences (such as work in VAMC environmental management services, food services, delivery services, or community jobs in food or other service delivery environments) that were not necessarily individualized to the patient's long-term preferences and had very little integration with the mental health treatment team. The VRP specialist assisted the veteran in a limited search for place-

ment in a competitive job that was delayed until after the set-aside work experience neared completion and provided time-limited follow-along support during the set-aside work experience, with little or no long-term follow-up vocational assistance after the first competitive job was obtained.

#### **Assessment procedures**

After providing informed consent at baseline, participants underwent a psychiatric and general medical evaluation, including a medical history, psychiatric history, and family psychiatric history. The clinical research coordinator recorded a comprehensive history of level of education, past em-

ployment, housing, relationships, major traumatic life events, and disability status. The clinical research coordinator also evaluated the participant for PTSD and other axis I disorders using the Mini-International Neuropsychiatric Interview (19). Participants were instructed to keep a job log formatted in a daily calendar that captured whether they were employed, number of hours worked, wages earned, and reasons for missed work. At baseline and one-, two-, three-, four-, six-, eight-, ten-, and 12-month follow-up visits, the clinical research coordinator collected the participants' job logs and reviewed the calendar with the participant for com-

pleteness. The clinical research coordinator recorded on a case report form the number of job interviews, job offers, and jobs obtained and the type of jobs, number of hours worked, wages earned, and reasons for missed work or job termination for each week.

At the follow-up visits, a trained assessor administered the Clinician Administered PTSD Scale (20), Clinical Global Impression–Severity (21), 16-item Quick Inventory of Depressive Symptomatology–Clinician Rated (22), and the Clinical Global Impression–Improvement, and veterans completed the Quick Inventory of Depression Symptomatology–Self-Report, World Health Organization Disability Assessment Schedule II (23), Sheehan Disability Scale (24), and Davidson Trauma Scale (25). The assessors were kept blind to the intervention assignment. Although there was a concerted effort to maintain this blind, accidental unblinding occurred infrequently (exact frequency unknown), in which case the ratings were subsequently conducted by a different blinded rater.

To minimize attrition, the investigators provided thorough preenrollment education to all prospective participants about the study objectives and procedures to assess and confirm their commitment to and feasibility for long-term follow-up. If needed, the clinical research coordinator and assessor traveled to the participant's community for the participant's convenience. To enhance the rate of return and to address a loss-of-wage or transportation cost barrier, all participants received a modest payment for follow-up interviews, regardless of whether they continued in the IPS or VRP assignment.

### **Randomization**

After signing informed consent and undergoing baseline assessments, eligible participants were assigned to receive either IPS or VRP. Assignment was based on a randomization list that was prepared before the study began. The IPS supported employment was provided for 12 months, and the VRP was of variable time-limited service as determined by the Tuscaloosa VAMC's VRP pro-

gram limits. Participants were followed and assessed at 12 months after baseline, regardless of intervention adherence, employment status, type of discharge, or attrition from the IPS or VRP intervention.

### **Fidelity monitoring**

The IPS specialists received ongoing training and supervision via monthly conference calls and quarterly site visits by the national IPS consultant (RT). During these visits, the consultant also conducted fidelity monitoring, which included reviewing the IPS specialist's caseload, meeting with veterans from both IPS and VRP interventions, interviewing participants' clinical providers, interviewing participants' employers, and rating the adherence of the IPS intervention with the Supported Employment Fidelity Scale (26). The national consultant also conducted a Supported Employment Fidelity Scale assessment of VRP to ensure that the ratings were low—that is, that VRP remained different from the IPS intervention as was intended by the study design.

### **Outcome variables**

The primary outcome was whether the participant engaged in competitive employment (yes or no). Competitive employment was defined as a job for regular wages in a setting that was not set aside, sheltered, or enclaved, that is, the same job could be held by people without a mental illness or disability and was not a set-aside job in the VRP. Day labor (that is, pick-up cash-based day jobs for yard work, babysitting, manual labor, and so forth) and military drill were not counted as competitive employment; however, data on income from all sources were collected. Secondary outcomes included the proportions of eligible weeks, days, and hours worked and gross income earned in competitive employment. Eligible weeks were defined as those in which the participant was not encumbered by a set-aside job (that is, a set-aside job in the VRP condition) and in which the participant was active in the study (that is, weeks during which the participant had exited the study were not counted because determin-

ing whether the participant was employed was not possible).

### **Data-analytic procedures**

Using intent-to-treat analyses and two-tailed tests with significance set at  $p \leq .05$ , we compared rates of competitive employment (the primary hypothesis) with chi square tests and number of eligible weeks of competitive employment (the secondary hypothesis) with a Mann-Whitney test. We also compared groups on the number of weeks, days, and hours worked in a competitive job; gross wages earned from all sources; and gross wages earned from competitive jobs. The between-group difference was tested by using either a *t* test or a Mann-Whitney test, depending on the distribution of the variable. There was no imputation for employment outcomes during the weeks in which the participants exited early and were no longer in the study. We examined the time (number of weeks) until the first week worked in a competitive job and used a Kaplan-Meier survival analysis with a log-rank test to compare intervention groups. Participants who did not get a job were classified as censored at their final assessment point.

### **Results**

A total of 100 participants were assessed for eligibility, and 85 were randomly assigned to either IPS ( $N=42$ ) or VRP ( $N=43$ ). A total of 71 (84%) completed the one-year follow-up. Reasons for early exit included withdrawn consent ( $N=1$ ), relocation ( $N=3$ ), and incarceration ( $N=2$ ) for the IPS group; for the VRP group reasons were loss to follow-up ( $N=2$ ), relocation ( $N=5$ ), and incarceration ( $N=1$ ). [A CONSORT diagram illustrating recruitment and follow-up is available in an online appendix to this report at [ps.psychiatryonline.org](http://ps.psychiatryonline.org).]

The 85 randomly assigned participants had been unemployed for a mean  $\pm$  SD of  $18.9 \pm 42.0$  months (range of 0–240 months; median of four months). In addition to PTSD, the participants had the following axis I disorders: major depressive disorder ( $N=76$ , 89%), dysthymia ( $N=17$ , 20%), agoraphobia ( $N=46$ , 54%), panic disorder ( $N=50$ , 59%), social phobia ( $N=24$ , 28%), alcohol de-

**Table 2**

Baseline characteristics of veterans with posttraumatic stress disorder (PTSD) randomly assigned to individual placement and support (IPS) supported employment or the Veterans Health Administration Vocational Rehabilitation Program (VRP)

Variable	IPS		VRP		Test statistic <sup>a</sup>	df	p
	N	%	N	%			
Female	5	12	5	12	$\chi^2=.00$	1	.968
Race					$\chi^2=2.22$	2	.329
Caucasian	9	21	14	33			
African American	32	76	29	67			
Native American	1	2	0	0			
Marital status					$\chi^2=4.23$	4	.376
Never married	9	21	14	33			
Married	12	29	8	19			
Separated	7	17	4	9			
Divorced	13	31	17	40			
Education					$\chi^2=8.51$	4	.075
Less than a GED	2	5	0	0			
GED	6	14	1	2			
High school	15	36	25	58			
AA degree or technical school	15	36	12	28			
College	4	10	5	12			
Age	39.9±11.9		40.5±12.5		$z=-.19$		.85
Length of military service (years)	7.8±5.8		6.4±5.4		$z=-1.34$		.18
Baseline measure							
CAPS <sup>b</sup>	77.3±24.0		78.4±18.3		$t=-.32$	83	.747
QIDS-CR <sup>c</sup>	12.3±4.5		12.2±4.2		$t=-.06$	83	.955
CGI-S <sup>d</sup>	4.8±.9.0		5.0±1.0		$z=-1.32$	—	.188
DTS <sup>e</sup>	84.9±28.3		82.9±28.4		$z=-.56$	—	.575
WHODAS II <sup>f</sup>	82.6±19.6		81.1±20.5		$t=-.32$	83	.747
SDS <sup>g</sup>	20.2±6.0		21.1±7.7		$z=-1.15$	—	.252

<sup>a</sup> Z test is Mann-Whitney z.

<sup>b</sup> Clinician Administered PTSD Scale. Possible scores range from 0 to 136, with higher scores indicating greater severity.

<sup>c</sup> Quick Inventory of Depressive Symptomatology–Clinician Rating. Possible scores range from 0 to 27, with higher scores indicating greater severity.

<sup>d</sup> Clinical Global Impression–Severity. Possible scores range from 0 to 7, with higher scores indicating greater illness severity.

<sup>e</sup> Davidson Trauma Scale. Possible scores range from 0 to 136, with higher scores indicating greater severity.

<sup>f</sup> World Health Organization Disability Assessment Schedule II. Possible scores range from 0 to 100, with higher scores indicating greater disability.

<sup>g</sup> Sheehan Disability Scale. Possible scores range from 0 to 30, with higher scores indicating greater impairment.

pendence (N=36, 42%), alcohol abuse (N=18, 21%), drug dependence (N=31, 37%), and drug abuse (N=15, 18%). The baseline demographic characteristics and scores of the participants are shown in Table 2. There were no significant differences between groups.

Thirty-two of the 42 IPS participants (76%) gained competitive employment, compared with 12 of the 43 VRP participants (28%) ( $\chi^2=19.84$ ,  $df=1$ ,  $p<.001$ ). That is, veterans with PTSD who participated in IPS were 2.7 times more likely to gain competitive employment than those who received VRP. The number needed to treat was 2.07 (95% confidence interval=1.96–2.19). In other words, if three individuals received IPS and three received VRP, one more individual in the IPS intervention would get a competitive job. (Note that to treat 2.07 patients, three patients must be seen.)

While in the study, IPS participants worked in a competitive job an average of 42% of the eligible weeks and those assigned to VRP worked an average of 16% of the eligible weeks (Mann-Whitney z test,  $p<.001$ ). As shown in Table 3, other occupational outcomes also favored IPS.

The Kaplan-Meier survival curves in Figure 1 illustrate the time until first competitive job for each group. The IPS group achieved competitive employment significantly more quickly than the VRP group (log-rank Mantel Cox  $\chi^2=21.32$ ,  $p<.001$ ). Most job acquisition occurred within the first 20 weeks of the IPS program.

**Table 3**

Occupational outcomes of veterans with posttraumatic stress disorder who received individual placement and support (IPS) supported employment or the Veterans Health Administration Vocational Rehabilitation Program (VRP)

Outcome at 1 year	IPS (N=42)		VRP (N=43)		p <sup>a</sup>	Cohen's d	95% CI
	M	SD	M	SD			
Weeks competitively employed <sup>b</sup>	21.6	17.7	6.8	13.8	<.001	.93	.50–1.36
Days competitively employed	83.8	80.6	29.3	61.9	<.001	.76	.32–1.19
Hours competitively employed	656	661	236	494	<.001	.72	.29–1.15
Total gross 12-month income, competitive sources (\$)	9,264	13,294	2,601	6,009	<.001	.65	.21–1.28
Total gross 12-month income, all sources (\$)	9,308	13,449	3,909	6,212	.05	.52	.08–.95

<sup>a</sup> Mann-Whitney z.

<sup>b</sup> Competitive employment refers to a job for regular wages in a setting that was not set aside, sheltered, or enclaved; that is, the same job could be held by an individual without a mental illness or disability and was not a set-aside job in the VRP. Day labor (that is, pick-up, cash-based day jobs for yard work, babysitting, manual labor, and so forth) and military drill were not counted as competitive employment.

The IPS fidelity monitor scored the Supported Employment Fidelity Scale as 55 at the onset of the study, and this score steadily improved to within a range of 58–65 during the study, with a mean±SD score of 61.2±2.1. On this scale, 66–77 is regarded as good IPS implementation, 56–65 as fair implementation, and ≤55 as “not supported employment.” The VRP was consistently rated by the fidelity monitor as ≤40 during the study, which is appropriate for this intervention.

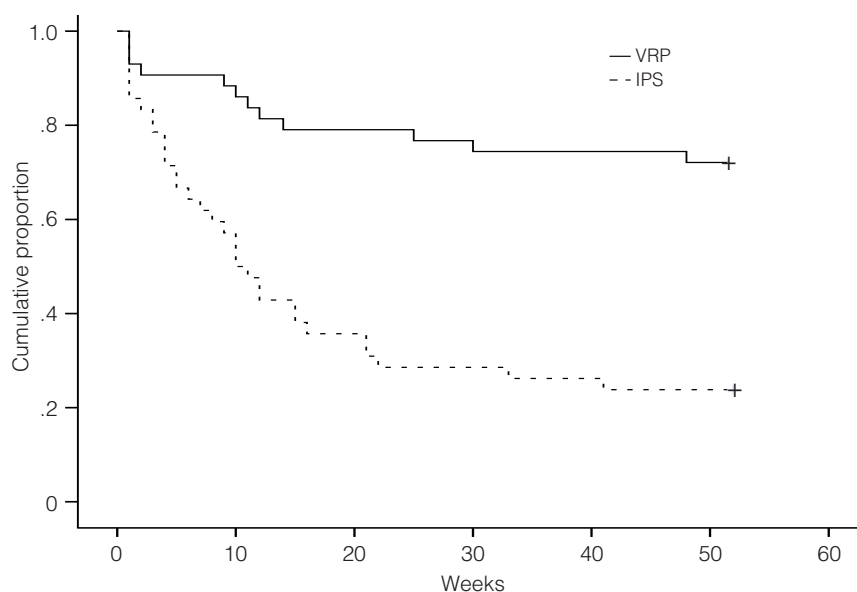
## Discussion

This study was the first to examine IPS supported employment outcomes for veterans with PTSD. Compared with those who received standard VRP services, unemployed veterans with PTSD who received IPS were 2.7 times more likely to gain competitive employment. Other employment outcomes, including time worked and total earnings, also favored IPS. These findings were consistent with previously reported advantages of IPS over traditional VRP (11). More than a dozen randomized controlled trials have shown that IPS enhances vocational outcomes among patients with severe and persistent mental disorders. Moreover, the effect size in our study was similar to those in previous studies. Studies in samples of individuals with serious mental illness have consistently shown that 42%–78% of individuals who receive IPS gain competitive employment. In our study, 76% of veterans with PTSD who received IPS gained competitive employment compared with 28% of those assigned to VRP. The results for VRP in our study were consistent with those in a recent VA report that 30% of veterans with PTSD were competitively employed at discharge from a VA VRP program (9).

The strengths of our study include its randomized controlled trial design, fidelity monitoring, and frequent follow-up assessments over one year. Limitations included the single study site, the limited number of IPS interventionists, and exclusion of nonveterans. A multisite trial with a larger and more diverse study sample would confirm the results and allow examination of secondary outcomes, such as PTSD

**Figure 1**

Time from randomization until first competitive employment among veterans receiving individual placement and support (IPS) supported employment or the Vocational Rehabilitation Program (VRP)



symptoms, quality of life, and other such outcomes. In addition, a larger study could evaluate the cost-effectiveness of the IPS intervention.

## Conclusions

In conclusion, occupational outcomes for veterans with PTSD were significantly better with the evidence-based IPS intervention than with a standard VA VRP. Our study was the first study of IPS to focus exclusively on individuals with PTSD and the first to directly compare the outcomes of IPS and VRP. The results of this study suggest that the VHA should consider changing its current guidelines for vocational services and provide IPS as a commonly available alternative intervention—and perhaps a preferred intervention—for all unemployed veterans with PTSD. IPS supported employment is patient centered in that it comprehensively addresses individual vocational needs, potentially enhancing clinical recovery and quality of life for veterans with PTSD. Given the large number of veterans returning from Operation Enduring Freedom, Operation Iraqi Freedom, Operation New Dawn, and other Southwest Asia deployments who often experience PTSD and confront unemployment upon military discharge, this study

was timely and has critical implications for clinical care and vocational rehabilitation programming in the VA and elsewhere.

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